DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0045]

Agency Information Collection Activities; Proposed Collection; Comment Request; Health and Diet Survey—ZOO4 Supplement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA] is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a voluntary consumer survey to gauge consumer understanding of diet-disease relationships, particularly those related to saturated fats, trans fatty acids, and omega-3 fatty acids, and consumer attitudes toward diet, health, and physical activity.

DATES: Submit written or electronic comments on the collection of information by *[insert date* 60 *days after date* of *publication in the* **Federal Register].**

ADDRESSES: Submit electronic comments on the collection of information to: ***http://www.fda.gov/dockets/ecomments*** Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

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20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; **(3)** ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Health and Diet Survey—2004 Supplement

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)). The Health and Diet Survey—2004 Supplement will provide FDA with information about consumers' knowledge of dietary fats and the risk of coronary heart disease as well as consumers' attitudes toward diet, health, and physical activity. A total of 2,200 adults in the 50 states and the District of Columbia will be interviewed by telephone. Participation will be voluntary. The survey will collect information concerning the following items: (1) Knowledge of the relationships between the risk of heart disease and dietary fats, including saturated fat, trans fatty acids, hydrogenated oil, omega-3 fatty acids, monounsaturated fats, and polyunsaturated fats; (2) attitudes toward diet, health, and physical activity; and (3) demographics and health status.

The agency has established specific targets to improve consumer understanding of diet-disease relationships, and in particular, the relationships between dietary fats and the risk of coronary heart disease, the leading cause of death in the United States. **FDA** intends to evaluate and track consumer understanding of heart-healthy and heart-harmful fats (saturated fat, trans fatty acids, and omega-3 fatty acids) as initial outcome measures of its achievement in improving public health. The primary purpose of the information collected in the survey will be to gauge current levels of consumer Understanding. The establishment of a baseline of consumer understanding will be useful for the development of performance indicators to identify and measure incremental improvement in consumer understanding. A secondary purpose of the information will be to increase the agency's understanding of consumers'

attitudes toward diet, health, and physical activity. This information will provide insight for the exploration of effective communication strategies and messages to assist consumers in making informed dietary and lifestyle choices.

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	27	1	27	0.5	13.5
Screener	6,000	1	6,000	0.02	120
Survey	2,000	1	2,000	0.17	340
Survey ("initial refusers")	200	1	200	0.08	16
Total					490

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience with previous consumer surveys. Prior to the administration of the survey, the agency plans to conduct a pretest of the final questionnaire to examine and reduce potential problems in survey administration The pretest will be conducted in three waves, each with nine respondents. The agency will use a screener to select an eligible adult respondent in each household to participate in the survey. Target sample size of the survey is 2,000 respondents who complete the interview. The agency, as part of an effort to increase survey participation, plans to re-contact and complete the interview with prospective respondents who refuse to participate at initial contacts. Two hundred of those who refuse for the second time, defined as "initial refusers," will be administered a shorter interview about their knowledge of saturated fat, trans fatty acids, omega-3 fatty acids, and the risk of coronary heart disease.

Dated: 2/10/04

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February 10, *2004.*

Jeffrey Shuren,

Assistant Commissioner for **Policy.**

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